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(54) Title: CLEAR HERBAL EXTRACT SOLUTIONS

(57) Abstract

A clear herbal extract solution, suitable for encapsulation in a soft gelatin capsule, wherein the said clear herbal solution includes: a concentrated herbal extract that is unsuitable by itself for direct encapsulation in a soft gelatin capsule; and a fill liquid; wherein the fill liquid is compatible with the herbal extract and is specific for dissolving the herbal extract to form a clear solution.

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CLEAR HERBAL EXTRACT SOLUTIONS

The present invention relates to clear herbal extract solutions which are suitable for encapsulation in a soft gelatin capsule. The invention also relates to soft gelatin capsules containing such solutions and methods for producing the same.

Natural herbs have been used as medicinal agents for many years. Whole plants or parts of the raw plant can be swallowed or applied topically for a therapeutic effect. This approach is generally inefficient as the active components only constitute a low proportion of such herb plant material. Further, the active components are only variably released from the herb plant material and appropriate dosages are difficult to obtain. The herb plant material itself is generally bulky and inconvenient to store, carry and use.

More recently, the active components have been extracted from the herbal plant material by various techniques including maceration, percolation or distillation. The extracts may then be formulated into a tablet or capsule form, which provides a more convenient form in which to administer the herbal extract. Extraction processes have been carried out using a variety of extracting solvents, for example various common liquids such as water, and/or ethanol. This extraction process can readily result in a concentrated liquid or a semi-liquid herbal extract material. To use the herbal extract, the liquid or semi-solid liquid may be dispersed onto a carrier material and the volatile extracting liquids evaporated. The resultant solid powder, with its adsorbed, absorbed or admixture of herbal extract may then be used to mix with solid excipient materials to make tablets or hard shelled capsules.

The same solid powder material can be mixed with suitable liquid excipient materials to make the fill material for soft gelatin encapsulation. However, the fill material is a slurry or a suspension. The resultant soft gelatin capsule is inelegant and subject to leakage at the seam if the powdered

material gets caught in the seam during encapsulation. Additionally, many of the powders (for example, dri d glucose syrup) upon which the herbal extract is dispersed, are not suitable for encapsulation in soft gelatin capsules because they cause shell hardening and loss or release of the fill material upon storage.

A number of the liquids created by the concentration process may be suitable for encapsulation directly. Many of these liquids are oils and are not added to solid excipients for tabletting purposes. They are made specifically for encapsulation as soft gelatin capsules. Such oils include evening primrose oil, peppermint oil, garlic oil and juniper berry oil. Some of these oils, for example garlic oil, are also commonly diluted with suitable excipient oils such as soya bean oil to make a clear solution which may also be encapsulated as a soft gelatin capsule. Such dilution is done purely for dosage and consumer use convenience, and is unrelated to the ability to encapsulate the fill material.

However, there are a number of liquids and semi-solid materials created by the concentration process which are too viscous and generally unsuitable for direct encapsulation into soft gelatin capsules. Dispersing the liquid herbal extracts onto a carrier material will not, in itself create a suitable material for direct encapsulation of the powdered or granular material in a soft gelatin capsule. Further, it has been found that clear solutions of such herbal extracts are desirable because of their marketing appeal. It has previously not been possible to formulate these herbal extracts into a clear liquid that is suitable for encapsulation in a soft gelatin capsule. Such materials have been discarded as being not suitable for soft gelatin encapsulation.

The present invention aims to overcome or at least alleviate one or more of the difficulties associated with the prior art.

It has now been found that by careful selection of a fill liquid which is compatibl with the concentrated herbal extract, whether in a visc us liquid form or disp rsed on a carrier material, that a cl ar solution may be formed

which has appropriate physical properties for encapsulati n into soft gelatin capsules. The fill liquid may be an xcipient or have its own th rapeutic activity.

Accordingly, in a first aspect of the present invention there is provided a clear herbal extract solution suitable for encapsulation in a soft gelatin capsule, wherein said clear herbal solution includes:

a concentrated herbal extract that is unsuitable by itself for direct encapsulation in a soft gelatin capsule, and

a fill liquid;

wherein the fill liquid is compatible with the herbal extract and is specific for dissolving the herbal extract to form a clear solution.

The concentrated herbal extract may be obtained by extraction processes, for example extracting solvents may be used, for example alcohols such as methanol or ethanol, water, acetone, ethyl acetate, glycerol, diethyl ether, propylene glycol or mixtures thereof, or when the herbal extract is generally hydrophobic, aliphatic hydrocarbons such as hexane, aromatic hydrocarbons such as toluene or benzene, or liquid gases such as liquid carbon dioxide may be used, or the extract may be obtained by a cold pressing technique. The resultant extract is then concentrated by evaporating all, or the majority of the solvent leaving a concentrated herbal extract.

The concentrated herbal extract may be unsuitable by itself for direct encapsulation into a soft gelatin capsule for a number of physical or chemical reasons. The invention is particularly applicable, although not limited to, those circumstances where the concentrated herbal extract is unsuitable for physical reasons such as being simply too viscous for encapsulation. Heating a viscous extract to reduce the viscosity is inappropriate as the warm solution may adversely effect the encapsulation process. Alternatively, the concentrated h rbal extract may be disp rsed on to a carrier material such as maltodextrin, dried glucose syrup or dicalcium phosphate, however the concentrated herbal

extract will remain unsuitable for direct encapsulati n as it will not result in a clear herbal solution, and the carrier mat rial may interact with the gelatin shell causing degradation or hardening of the shell.

In order to obtain a clear herbal extract solution suitable for encapsulation in a soft gelatin capsule, the concentrated herbal extract is dissolved in a compatible fill liquid. The compatibility of the fill liquid is largely dependent upon the hydrophilicity/hydrophobicity of the concentrated herbal extract and the solubility of any carrier material. For example, if the herbal extract is hydrophilic in nature, as would be the case when water and/or ethanol are used as the extracting solvent, a hydrophilic fill liquid, preferably a polyethylene glycol of molecular weight of from 300 to 8,000, may be used. The fill liquid may be a blend of polyethylene glycol with another polyol of molecular weight from 50 to 8,000, for example, a blend with propylene glycol and/or glycerol. Most preferably, the fill liquid is Macrogol 400 or a blend of Macrogol 400 with another polyol. Water may also be included in an amount of up to about 30%.

Similarly, if the herbal extract is hydrophobic, such as an oily liquid or semi-solid, a hydrophobic fill liquid such as a medium chain triglyceride or vegetable oil or a vegetable oil derivative such as a hydrogenated vegetable oil. Examples of suitable hydrophobic fill liquids include:

Almond Oil,
Arachis Oil,
Borage Oil,
Canola Oil,
Evening Primrose Oil,
Fractionated Coconut Oil,
Lecithin,
Linseed Oil,
Maize Oil,

Oliv Oil,
Rapeseed Oil,
Rice Bran Oil,
Safflower Oil,
Soya Bean Oil,
Spearmint Oil,
Sunflower Oil,
Wheatgerm Oil.

For ease of transportation, storage and further processing, the concentrated herbal extract may be dispersed onto a carrier material, such as maltodextrin, dried glucose syrup or dicalcium phosphate. Extracts dispersed onto carrier materials are a dry powder or granular material and are generally not suitable for directly encapsulating into a soft gelatin capsule. They are generally used to make hard capsules or tablets or are mixed to form a slurry for encapsulation in a soft gelatin capsule. In order to avoid the inherent encapsulation problems of slurries or suspensions, the powdered or granular herbal extracts may be formulated into a clear solution by selection of an appropriate fill liquid that matches the hydrophilicity of the herbal extract and is capable of dissolving the extract.

Preferably, the fill liquid is selected that is also able to dissolve the carrier material to form a clear solution. That cannot always be achieved. In such circumstances a fill liquid should be selected that is able to dissolve the concentrated herbal extract to form a clear herbal solution. The carrier material may be filtered out prior to encapsulation of the clear herbal solution. The near clear solution may be filtered through a standard filter, for example a 5 µm felt bag to remove any undissolved carrier material.

By carefully selecting and matching the hydrophilicity/hydrophobicity of th concentrated herbal xtract and the solubility of any carrier mat rial and the fill liquid, a clear solution may be form d that is suitable for encapsulation in a

soft gelatin capsule. The clear solution is less viscous than the concentrated herbal extract, as the herbal extract is in a dissolved form in the fill liquid. Further, removing the carrier material by either dissolving the carrier material in the fill liquid, or removing the carrier material by filtering, produces a clear solution.

Herbal extracts that are suitable for encapsulation in accordance with the present invention include:

Achillea millefolium (Yarrow) herb,
Agropyron repens (Couch Grass) root,
Althaea officinalis (Marshmallow) root,
Angelica polymorpha (Dong Quai) root,
Apium graveolens (Celery) seed,
Arctium lappa (Burdock) root,
Arctostaphylos uva-ursi (Uva-Ursi) leaf,
Armoracia rusticana (Horse Radish) root,
Artemisia annua (Chinese wormwood) herb,
Astragalus membranaceus (Milk vetch) root,
Avena sativa (Oats) herb,
Barosma betulina (Buchu) leaf,
Berberis vulgaris (Barberry) root,
Boswellia serrata (Olibanum) gum oleoresin,
Calendula officinalis (Marigold) flower,
Camelia sinensis (Green Tea) leaf,
Cassia senna (Senna) fruit,
Caulophyllum thalictroides (Blue Cohosh) root,
Centaurium erythraea (Centaury) herb,
Centella asiatica (Gotu Kola) herb,
Chelidonium majus (Greater celandine) herb,
Cimicifuga racemosa (Black Cohosh) root,
Cola nitida (Kola) cotyledon,

Crataegus laevigata (Hawthorn) herb,

Crataegus monogyna (Hawthorn) herb,

Curcuma longa (Turmeric) rhiz me,

Cynara scolymus (Globe Artichoke) leaf,

Dioscorea villosa (Wild Yam) root,

Echinacea angustifolia root & rhiz.,

Echinacea purpurea (Echinacea) herb,

Echinacea purpurea (Echinacea) root and rhiz.,

Eleutherococcus senticosus (Siberian Ginseng) root,

Epilobium parviflorum (Small leafed willow) herb,

Equisetum arvense (Horsetail) herb,

Eschscholtzia californica (Californian Poppy) flower,

Eupatorium perfoliatum (Boneset) herb,

Euphorbia hirta (Euphorbia) herb,

Euphrasia officinalis (Eyebright) herb,

Filipendula ulmaria (Meadowsweet) herb,

Fucus vesiculosus (Kelp) herb,

Galium aparine (Clivers) herb,

Garcinia quaesita (Garcinia) fruit,

Gentiana lutea (Gentian root & rhiz.),

Ginkgo biloba (Maidenhair tree) leaf,

Glycine max (Soya Bean) seed,

Glycyrrhiza glabra (Liquorice) root,

Grindelia robusta (Grindelia) herb,

Hamamelis virginiana (Hamamelis) leaf,

Harpagophytum procumbens (Devil's Claw) root,

Humulus lupulus (Hops) fruit,

Hydrangea arborescens (Wild Hydrangea) flower,

Hydrastis canadensis (Golden Seal) root,

Hypericum perforatum (St John's Wort) herb,

Ilex paraguariensis (Mate) leaf,

Inula helenium (Elecampane) root,

Malpighia punicifolia (Acer la) fruit,

Matricaria recutita (German Chamomille) flow r,

Medicago sativa (Alfalfa) leaf,

Melissa officinalis (Balm) leaf,

Olea europaea (Olive tree) leaf,

Ononis spinosa (Spring rest-harrow) root,

Orthosiphon stamineus (Java tree) leaf,

Panax ginseng (Korean Ginseng) root,

Passiflora incarnata (Passionflower) herb,

Paullinia cupana (Guarana) seed,

Petroselinum crispum (Parsley) seed,

Peumus boldus (Boldo Tree) leaf,

Piper methysticum (Kava kava) root,

Piscidia piscipula (Jamaica Dogwood) root bark,

Prunus domestica (Prune) fruit,

Pueraria lobata (Kudzu vine) root,

Rhamnus purshianus (Cascara) bark,

Rosa canina (Dog Hip Rose) fruit,

Rosmarinus officinalis (Rosemary) leaf,

Rumex crispus (Yellow Dock) root,

Salix alba (White Willow) bark,

Salvia officinalis (Sage) leaf,

Sambucus nigra (Black elder) flower,

Schizandra chinensis (Chinese mongolavine) fruit,

Scutellaria lateriflora (Skullcap) herb,

Serenoa serrulata (Saw Palmetto) fruit,

Silybum marianum (Milk Thistle) seeds,

Silybum marianum (Silymarine) fruit,

Smilax officinalis (Sarsaparilla) root/rhiz.,

Solidago vigaurea (Golden Rod) herb,

Tabebuia avellaneda (Pau d'arco) stem bark,

Taraxacum officinale (Dandelion) herb,

Thymus vulgaris (Common Thyme) herb,
Tilia cordata (Lime Tree) flower,
Tribulus t rrestris (Burra gokhru) fruit,
Trifolium pratense (Red Clover) flower,
Turnera diffusa (Damiana) leaf,
Uncaria tomentosa (Cat's Claw) stem bark,
Urtica dioica (Nettle) root,
Vaccinium myrtillus (Bilberry) fruit,
Valeriana officinalis (Valerian) root,
Vanilla planifolia (Vanilla) fruit,
Verbena officinalis (Vervain) herb,
Viburnum opulus (Cramp bark) twig bark,
Viola odorata herb,
Viscum album (Mistletoe) herb,
Vitex agnus castus (Chaste Tree) fruit,
Vitis vinifera (Grapeseed) seed,
Withania somnifera (Winter Cherry) root,
Yucca elata (Palmella) root,
Zanthoxylum americanum (Prickly ash) bark,
Zea mays (Corn) styles and stigmas,
Zingiber officinale (Ginger) rhizome,
Zizyphus spinosa (Chinese jujube) fruit.

Examples of herb extracts which have been found to be dissolved in a hydrophilic liquid fill such as Macrogol 400 or mixtures with other polyols include; Globe Artichoke, Ginkgo Biloba, Turmeric, Soy Isoflavone, Hypericum, Ginseng, Echinacea angustifolia, Dong Quai, Black Cohosh, Epilobium, Zizyphus and Olive Leaf. Examples of herb extracts which have been found to be dissolved in a hydrophobic liquid fill such as soya bean oil include; Ginger extracts and Saw Palmetto extracts.

The clear herbal solution may also include a number of herbal extracts and fill liquids in the same s lution. The combination of herbal extracts and fill liquids is however dependent upon the formation of a clear solution that will not interact in a detrimental manner with the gelatin shell.

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According to a further aspect of the present invention, there is provided a soft gelatin capsule containing the clear herbal extract solution of the invention, wherein said herbal extract solution includes a concentrated herbal extract which is unsuitable by itself for direct encapsulation in a soft gelatin capsule,
10 and

a fill liquid;

wherein the fill liquid is compatible with the herbal extract and is specific for dissolving the herbal extract to form a clear solution.

15 A soft gelatin capsule may contain any suitable amount of active herbal extract for therapeutic purposes. Typically this may range from 1 mg to 1000 mg of active ingredient per capsule depending upon the extract, however variations outside the range may also be contemplated.

20 The soft gelatin capsule preferably includes a shell comprising a mixture of gelatin, water and a polyol, preferably glycerol. In one form the shell may be clear and uncoloured providing a completely transparent capsule. The shell may also be coloured with appropriate dye material to provide a clear coloured shell and hence a coloured transparent capsule.

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In yet a further aspect of the present invention there is provided a process for manufacturing a clear soft gelatin capsule, said process including the steps of :

(i) combining a concentrated herbal extract that is unsuitable by itself
30 for direct encapsulation in a soft gelatin capsule, with a fill liquid capable of dissolving the herbal extract to form the clear herbal extract solution of the invention suitable for encapsulation; and

(ii) encapsulating said herbal extract solution in a soft gelatin capsule.

The combination of the concentrated herbal extract and fill liquid is preferably raised to an elevated temperature, most preferably in the range of from 50° to 80°C with gentle stirring prior to encapsulation to optimise solubilisation.

The concentrated herbal extract may be dispersed upon a carrier material prior to combining with the fill liquid. In such circumstances, either a fill liquid is selected that will also dissolve the carrier material or if the carrier material does not dissolve or is only partially dissolved, the process includes the additional step of filtering the carrier material from the clear herbal solution prior to encapsulation. An example of how the solution may be filtered is to pass the solution in through a 5 µm felt bag. It has been found that there is no loss of active material following the filtering process.

The concentrated herbal extract and the fill liquid should be combined in a ratio that is sufficient to dissolve the herbal extract completely yet maintain a therapeutic concentration of the herbal extract. Suitable ratios of concentrated herbal extract to fill liquid range from 1:100 to 3:1.

Other additives may also be included in the solution including emulsifiers, stabilisers and dyes.

The present invention is not limited to the use of a single herbal extract, or indeed a single fill liquid. It is possible to use a mixture of excipients and/or herbal extracts to create a clear solution. Alternatively a mixture of fill liquids and/or herbal extracts may be used to make a micro-emulsion with the inclusion of a suitable emulsifier.

A particular advantag of th present invention is that certain concentrated herbal extracts may be encapsulated in a soft gelatin capsul as a clear solution, that were previously unsuitable for direct encapsulation. This is achieved by identifying the appropriate fill liquid that is able to dissolve the concentrated herbal extract.

The present invention will now be described with reference to the following examples. It should be kept in mind that these examples are merely illustrative of the present invention and the scope should not be considered to be limited thereto.

EXAMPLE 1

A concentrated soft extract of ginger that had been extracted with liquid carbon dioxide was obtained. The ginger extract was dissolved in soya bean oil to form a clear solution, which was then encapsulated. The formulation of the final product is:

Active fill solution	
Ginger Extract	264.0 mg
Soya Bean Oil	146.0 mg
Soft gelatin shell	
Gelatin	120.0 mg
Glycerol	53.2 mg
Water	15.1 mg

EXAMPLE 2

A concentrat d soft extract of Saw Palmetto that had been extracted with liquid carbon dioxid was obtained. This is a brownish-yellow oily solution.

This oily solution was combined with an appropriate quantity of soya bean oil, which resulted in a clear brownish yell w solution. When this was encapsulated in a clear gelatin capsule, the end formulation was:

Active fill solution

Saw Palmetto Extract	80.0 mg
Soya Bean Oil	320.0 mg

Soft gelatin shell

Gelatin	118.1 mg
Glycerol	54.4 mg
Water	14.0 mg

EXAMPLE 3

A concentrated soft extract of Saw Palmetto that had been extracted with liquid carbon dioxide was obtained. This is a brownish-yellow oily solution. This oily solution was combined with an appropriate quantity of soya bean oil, which resulted in a clear brownish yellow solution. When this was encapsulated in a clear gelatin capsule, the end formulation was:

Active fill solution

Saw Palmetto Extract	500 mg
Soya Bean Oil	500 mg

EXAMPLE 4

A concentrated dry extract of Ginkgo Biloba leaves was obtained from a hydrophilic solvent. The extract was combin d with a combination of fill liquids.

After filtration, this was encapsulated in a clear gelatin capsule, the end formulation of the active fill material was:

Active fill material

Ginkgo Biloba Leaves Extract (equivalent)	50 mg
Polyethylene Glycol 400	952.5 mg
Glycerol	95 mg
Water	62.5 mg

EXAMPLE 5

A concentrated dry extract of Turmeric was obtained from a hydrophilic solvent. This was a yellow powder. This powder was combined with a combination of fill liquids and filtered to produce a clear red solution. When this was encapsulated in a clear gelatin capsule, the end formulation of the active fill material was:

Active fill material

Turmeric Extract (equivalent)	170 mg
Polyethylene Glycol 400	715 mg
Propylene Glycol	65 mg
Water	50 mg

EXAMPLE 6

A concentrated dry extract of Soy Isoflavone was obtained from a hydrophilic solvent. The extract was combined with a combination of fill liquids. After filtration this was encapsulated in a clear gelatin capsule, the end formulation of the activ fill material was:

Active fill material

Soy Isoflavone Extract (equivalent)	185 mg
Polyethylene Glycol 400	741 mg
Propylene Glycol	74 mg

EXAMPLE 7

A concentrated dry extract of Hypericum Herb was obtained from a hydrophilic solvent. The extract was combined with a combination of fill liquids. After filtration, this was encapsulated in a clear gelatin capsule, the end formulation of the active fill material was:

Active fill material

Hypericum Herb Extract (equivalent)	126 mg
Polyethylene Glycol 400	757.4 mg
Propylene Glycol	75.6 mg
Water	126 mg

EXAMPLE 8

A concentrated dry extract of Korean Ginseng Root was obtained from a hydrophilic solvent. The extract was combined with a combination of fill liquids. After filtration, this was encapsulated in a clear gelatin capsule, the end formulation of the active fill material was:

Active fill material

Korean Ginseng Root Extract (equival nt)	39.2 mg
Polyethylene Glycol 400	45.5 mg
Propylene Glycol	7.6 mg
Water	7.6 mg

EXAMPLE 9

A concentrated dry soft extract of Globe Artichoke was obtained from a hydrophilic solvent. The extract was combined with a combination of fill liquids. After filtration, this was encapsulated in a clear gelatin capsule, the end formulation of the active fill material was:

Active fill material

Globe Artichoke Extract (equivalent)	200 mg
Water	90 mg
Polyethylene Glycol 400	750 mg
Propylene Glycol	90 mg

By (equivalent) in examples 4 to 9, we mean equivalent to the dry extract.

Finally, it will be appreciated that many variations, modifications and alterations may be made to the above described invention without departing from the spirit or ambit of the invention. It should be considered that the invention encompasses the variations.

CLAIMS

1. A clear herbal extract solution, suitabl for encapsulation in a soft gelatin capsule, wherein the said clear herbal solution includes:

a concentrated herbal extract that is unsuitable by itself for direct encapsulation in a soft gelatin capsule; and

a fill liquid;

wherein the fill liquid is compatible with the herbal extract and is specific for dissolving the herbal extract to form a clear solution.

2. A clear herbal solution according to claim 1, wherein the concentrated herbal extract has been obtained by a cold pressing or extraction process and is a liquid or semi-solid material, that is unsuitable by itself for direct encapsulation in a soft-gelatin capsule, and optionally, has been dispersed on a carrier material.

3. A clear herbal solution according to claim 1 or 2, wherein the concentrated herbal extract has been extracted with a hydrophilic solvent.

4. A clear herbal solution according to claim 3 wherein the hydrophilic solvent is selected from water, ethanol, methanol, acetone, ethyl acetate, glycerol, diethyl ether, propylene glycol or mixtures thereof.

5. A clear herbal solution according to claim 3 or 4 wherein the fill liquid is hydrophilic.

6. A clear herbal solution according to claim 5 wherein the fill liquid is a polyethylene glycol having a molecular weight of from 300 to 8,000, or a mixture of a polyethylene glycol with one or more other polyols having a molecular weight of from 50 to 8,000.

7. A clear herbal solution according to claim 6 wherein the polyol is selected from propylen glycol, glycerol or another polyethylene glycol.

8. A clear herbal solution according to claim 6 or 7, wherein the polyethylene glycol is Macrogol 400.

9. A clear herbal solution according to any one of claims 3 to 8 wherein the herbal extract is selected from Globe Artichoke, Ginkgo Biloba, Turmeric, Soy Isoflavone, Hypericum, Ginseng, Echinacea angustifolia, Dong Quai, Black Cohosh, Epilobium, Zizyphus and Olive Leaf.

10. A clear herbal solution according to claim 1 or 2 wherein the concentrated herbal extract has been extracted with a hydrophobic solvent or cold pressing.

11. A clear herbal solution according to claim 10, wherein the hydrophobic solvent is an aliphatic hydrocarbon, an aromatic hydrocarbon, or liquid carbon dioxide or mixtures thereof.

12. A clear herbal solution according to claim 11 wherein the aliphatic hydrocarbon is hexane, and the aromatic hydrocarbon is benzene or toluene.

13. A clear herbal solution according to any one of claims 9 to 11, wherein the fill liquid is hydrophobic.

14 A clear herbal solution according to any one of claims 9 to 12 wherein the fill liquid is a vegetable oil, vegetable oil derivative or a medium chain triglyceride.

15. A clear herbal solution according to claim 14 wherein the vegetable oil is selected from:

Almond Oil,
Arachis Oil,
Borage Oil,
Canola Oil,
Evening Primrose Oil,
Fractionated Coconut Oil,
Lecithin,
Linseed Oil,
Maize Oil,
Olive Oil,
Rapeseed Oil,
Rice Bran Oil,
Safflower Oil,
Soya Bean Oil,
Spearmint Oil,
Sunflower Oil,
Wheatgerm Oil.

16. A clear herbal solution according to any one of claims 10 to 15 wherein the herbal extract is selected from Ginger and Saw Palmetto.

17. A clear herbal solution according to any of claims 2 to 16 wherein the carrier material is selected from maltodextrin, dried glucose syrup or dicalcium phosphate.

18. A soft gelatin capsule containing a clear herbal solution according to any one of the preceding claims.

19. A soft gelatin capsule according to claim 18 wherein the shell of the capsule comprises a mixture of gelatin, a suitable polyol and water.

20. A soft gelatin capsule according to claim 18 wherein th polyol is glycer l.

21. A soft gelatin capsule according to any one of claims 18 to 20 wherein the shell of the capsule is either transparent, or coloured to provide a clear coloured shell.

22. A soft gelatin capsule according to any one of claims 18 to 21 wherein the capsule contains from 1 mg to 1000 mg of active herbal extract.

23. A process for manufacturing a clear soft gelatin capsule, including the steps of:

(i) combining a concentrated herbal extract that is unsuitable by itself for direct encapsulation in a soft gelatin capsule, and a fill liquid which is compatible with the herbal extract and specific for dissolving the herbal extract to form the clear herbal solution according to any one of claims 1 to 17; and

(ii) encapsulating said herbal extract in a soft gelatin capsule.

24. A process according to claim 23, wherein the concentrated herbal extract, and the fill liquid are combined at a temperature of from 50° to 80°C, and mixed with slow stirring to optimise solubilisation.

25. A process according to claim 23 or 25 wherein the concentrated herbal extract is dispersed onto a carrier material prior to combining with the fill liquid, said process including the further steps of either:

(i) dissolving the carrier material with the fill liquid to form a clear herbal solution prior to encapsulation; and/or

(ii) filtering any undissolved carrier material from the clear herbal solution prior to encapsulation.

26. A process according to claim 25, wherein the carrier material is selected from maltodextrin, dried glucose syrup and dicalcium phosphate.

27. A clear herbal extract solution according to claim 1 or 2, a gelatin capsule according to any one of claims 18 to 21, or a process according to any one of claims 23 to 26, wherein the concentrated herbal extract is selected from a concentrated extract of:

Achillea millefolium (Yarrow) herb,
Agropyron repens (Couch Grass) root,
Althaea officinalis (Marshmallow) root,
Angelica polymorpha (Dong Quai) root,
Apium graveolens (Celery) seed,
Arctium lappa (Burdock) root,
Arctostaphylos uva-ursi (Uva-Ursi) leaf,
Armoracia rusticana (Horse Radish) root,
Artemisia annua (Chinese wormwood) herb,
Astragalus membranaceus (Milk vetch) root,
Avena sativa (Oats) herb,
Barosma betulina (Buchu) leaf,
Berberis vulgaris (Barberry) root,
Boswellia serrata (Olibanum) gum oleoresin,
Calendula officinalis (Marigold) flower,
Camelia sinensis (Green Tea) leaf,
Cassia senna (Senna) fruit,
Caulophyllum thalictroides (Blue Cohosh) root,
Centaurium erythraea (Centaury) herb,
Centella asiatica (Gotu Kola) herb,
Chelidonium majus (Greater celandine) herb,
Cimicifuga racemosa (Black Cohosh) root,
Cola nitida (Kola) cotyledon,
Crataegus laevigata (Hawthorn) herb,

Crataegus monogyna (Hawthorn) herb,
Curcuma longa (Turmeric) rhizome,
Cynara scolymus (Globe Artichoke) leaf,
Dioscorea villosa (Wild Yam) root,
Echinacea angustifolia root & rhiz.,
Echinacea purpurea (Echinacea) herb,
Echinacea purpurea (Echinacea) root and rhiz.,
Eleutherococcus senticosus (Siberian Ginseng) root,
Epilobium parviflorum (Small leafed willow) herb,
Equisetum arvense (Horsetail) herb,
Eschscholtzia californica (Californian Poppy) flower,
Eupatorium perfoliatum (Boneset) herb,
Euphorbia hirta (Euphorbia) herb,
Euphrasia officinalis (Eyebright) herb,
Filipendula ulmaria (Meadowsweet) herb,
Fucus vesiculosus (Kelp) herb,
Galium aparine (Clivers) herb,
Garcinia quaesita (Garcinia) fruit,
Gentiana lutea (Gentian root & rhiz.),
Ginkgo biloba (Maidenhair tree) leaf,
Glycine max (Soya Bean) seed,
Glycyrrrhiza glabra (Liquorice) root,
Grindelia robusta (Grindelia) herb,
Hamamelis virginiana (Hamamelis) leaf,
Harpagophytum procumbens (Devil's Claw) root,
Humulus lupulus (Hops) fruit,
Hydrangea arborescens (Wild Hydrangea) flower,
Hydrastis canadensis (Golden Seal) root,
Hypericum perforatum (St John's Wort) herb,
Ilex paraguariensis (Mate) leaf,
Inula helenium (Elecampane) root,
Malpighia punicifolia (Acerola) fruit,

Matricaria recutita (German Chamomille) flower,
Medicag sativa (Alfalfa) leaf,
Melissa officinalis (Balm) leaf,
Olea europaea (Olive tree) leaf,
Ononis spinosa (Spring rest-harrow) root,
Orthosiphon stamineus (Java tree) leaf,
Panax ginseng (Korean Ginseng) root,
Passiflora incarnata (Passionflower) herb,
Paullinia cupana (Guarana) seed,
Petroselinum crispum (Parsley) seed,
Peumus boldus (Boldo Tree) leaf,
Piper methysticum (Kava kava) root,
Piscidia piscipula (Jamaica Dogwood) root bark,
Prunus domestica (Prune) fruit,
Pueraria lobata (Kudzu vine) root,
Rhamnus purshianus (Cascara) bark,
Rosa canina (Dog Hip Rose) fruit,
Rosmarinus officinalis (Rosemary) leaf,
Rumex crispus (Yellow Dock) root,
Salix alba (White Willow) bark,
Salvia officinalis (Sage) leaf,
Sambucus nigra (Black elder) flower,
Schizandra chinensis (Chinese mongolavine) fruit,
Scutellaria lateriflora (Skullcap) herb,
Serenoa serrulata (Saw Palmetto) fruit,
Silybum marianum (Milk Thistle) seeds,
Silybum marianum (Silymarine) fruit,
Smilax officinalis (Sarsaparilla) root/rhiz.,
Solidago vigaurea (Golden Rod) herb,
Tabebuia avellanedae (Pau d'arco) stem bark,
Taraxacum officinale (Dandelion) herb,
Thymus vulgaris (Common Thyme) herb,

Tilia cordata (Lime Tree) flower,
Tribulus terrestris (Burra gokhru) fruit,
Trifolium pratense (Red Clover) flower,
Turnera diffusa (Damiana) leaf,
Uncaria tomentosa (Cat's Claw) stem bark,
Urtica dioica (Nettle) root,
Vaccinium myrtillus (Bilberry) fruit,
Valeriana officinalis (Valerian) root,
Vanilla planifolia (Vanilla) fruit,
Verbena officinalis (Vervain) herb,
Viburnum opulus (Cramp bark) twig bark,
Viola odorata herb,
Viscum album (Mistletoe) herb,
Vitex agnus castus (Chaste Tree) fruit,
Vitis vinifera (Grapeseed) seed,
Withania somnifera (Winter Cherry) root,
Yucca elata (Palmella) root,
Zanthoxylum americanum (Prickly ash) bark,
Zea mays (Corn) styles and stigmas,
Zingiber officinale (Ginger) rhizome,
Zizyphus spinosa (Chinese jujube) fruit.

28. A clear solution according to claim 1 substantially as hereinbefore described with reference to any one of the examples.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 98/00878

A. CLASSIFICATI N OF SUBJECT MATTER

Int Cl[6]: A61K 35/78, 9/08, 9/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: A61K 35/78, 9/08, 9/48

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU: IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT: LIQUID: OR CLEAR OR SOL: OR POLYETHYLENE(W) GLYCOL OR PEG OR MACROGOL
JAPIO: AND CAPSULE: AND GELATIN: OR ENCAPS: OR EXTRACT:
PUBMED: GINGER: OR GINSENG: OR GINKGO: and SOLUTION:

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 464274 A (STEPHAN, G) 8 January 1992 (Derwent Abstract Accession No: 92-009607/02, Class B07) Whole document	1-28
A	EP 496705 A (FLACHSMANN) 29 July 1992 (Derwent Abstract Accession No: 92-251882/31, Class B04)	
X	Veterinary Research, Vol. 26(3), 1995, pp 155-161, S. Hu, et al., "Ginseng enhanced oxidative and phagocytic activities of polymorphonuclear leucocytes from bovine peripheral blood and stripping milk" Whole document	1-28

☒ Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" Document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 November 1998	19 NOV 1998
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929	Authorized officer CEDRIC SCHAFFER Telephone No.: (02) 6283 2277

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 98/00878

C (Continuation). **DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	J. Pharm, Dyn , 7, 1984, pp 835-848, S. Mamoru et al., "Pharmacological Studies on Ginger, I. Pharmacological Actions of Pungent Constituents, (6)-Gingerol and (6) - Shogaol." Whole document	1-28
X	Materia Medica Polona: the Polish Journal of Medicine and Pharmacy, 1995, Oct-Dec; 27(4): pp 141-6, J. Wojcicki et al, "Comparative Pharmacokinetics and Bioavailability of Flavonoid Glycosides of Ginkgo Biloba after a single oral administration of three formulations to healthy volunhteers." Whole document	1-5, 9, 13, 23-25, 28

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 98/00878

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
EP	464274	DK	2510/89	EP	343575	FI	892524
		NO	892077	PT	90640	FI	912690
		NO	912177				
EP	496705	CH	683594	JP	6136253		

END OF ANNEX